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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,202	07/31/2001	James J. Huttner	1-15207	4606
7590	09/08/2004		EXAMINER	THANH, LOAN H
Donald A. Schurr Marshall & Melhorn, LLC 8th Floor Four SeaGate Toledo, OH 43604			ART UNIT	PAPER NUMBER
			3763	
			DATE MAILED: 09/08/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/919,202	HUTTNER, JAMES J.	
	<b>Examiner</b>	<b>Art Unit</b>	
	LoAn H. Thanh	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 June 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12,28-30 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-12 and 28-30 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 31 July 2001 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,7-10,12,28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Kravitz ( U.S. Patent No. 3,620,209).

Kravitz teaches a method of reducing pain associated with skin penetration at a site with a needle comprising urging a skin-engaging surface ( formed by 32 on the casing) of a pressure member 10 against the skin 12. It is inherent that stimulation of the large diameter afferent sensory fiber and blocking of pain signal from the small diameter afferent pain nerve fibers in the skin proximate the site occurs since the device of Kravitz is similar in structure with the claimed device of applicant. The aperture is considered to be 14 where the needle/ hypodermic syringe 16 is to be inserted.

Further, Kravitz discloses that the pain normally associated with the injection at the area is reduced or minimal. ( see abstract). Further, col. 2 lines 43-49, Kravitz further discloses that his device is for reducing pain of injection and to lessen the pain associated with such injections by pressing the device ( case 10) against the skin.

With respect to the functional language of “to thereby depress the skin with sufficient force”, the prior art is considered to be capable of performing the intended use lacking any further structural distinguishing features. The device is urged against the skin by

the strap of the band and in this respect will provide the reduction in the pain. Although applicant has a method claim, it is considered to be inherently encompassed by the use of Kravitz's device. Applicant is suggested to either claim a distinguishing structural feature or a distinguishing method step which is not inherently performed by the device of Kravitz.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kravitz (U.S. Patent No. 3,620,209).

Kravitz discloses the claimed invention except for the material of the pressure to be flexible, polymeric rigid or metal. Kravitz is silent to the materials of the pressure member. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the materials of the pressure member to suit the area to which it would be applied to , since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended uses as a matter of obvious engineering choice lacking any criticality. In re Leshin , 125 USPQ 416.

With respect to claim 11, Kravitz does not show a generally cloverleaf shape pressure member. It would have been an obvious design choice to modify the horseshoe or u-shaped design of the Kravitz device with a cloverleaf shape lacking any criticality of the shape. The Examiner is taking the position that matters relating to ornamentation only, which have no mechanical function, cannot be relied upon to patentably distinguish the claimed invention from the prior art. The particular shape of a product is of no patentable significance since it appears to be a matter of choice that a person of ordinary skill in the art would find obvious absent persuasive evidence that the particular configuration of the claimed container was significant. In re Dailey, 357 F.2d 669,149 USPQ 47 ( CCPA 1966).

### ***Response to Arguments***

Applicant's arguments filed 06/28/04 have been fully considered but they are not persuasive.

With respect to applicant's arguments on page 8, regarding the claim limitation of the skin engaging surface being "*relatively broad* in relation to the thickness of the pressure member" the Examiner is maintaining the rejection since the claim language is still broad, the prior art still encompasses the limitations. Broad is interpreted as "having ample extent from side to side or between limits" as defined by Merriam Webster's Dictionary (on-line) . Side to side of the device of Kravitz or between limits of Kravitz is considered relatively broad in relation to the thickness of the pressure member. The width of the pressure member is relatively broad in relation to the thickness of the

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pressure member. The other interpretation is that the skin engaging surface is relatively broad in relation to the thickness. The Examiner is not in agreement with applicant's assessment of the Kravitz reference as described since another interpretation is taken by the Examiner when considering the claim language. Applicant's language of "relatively broad in relation to" can be interpreted in a broad manner.

With respect to applicant's arguments on page 9, the Examiner's position is that applicant has claimed broadly that the material is a "flexible enough". Flexible is a relative term and modifying materials is considered to be well within the skill of one ordinary in the art. The motivation of wrapping the device of Kravitz to fit any size arms (from adult to child or obese to underweight) would be motivation to one of ordinary skill.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation is in the knowledge generally available to one of ordinary skill in the art. Patentability is not in the flexible material.

With respect to arguments regarding the shape of the device to be well within the skill of one of ordinary skilled in the art, the device would perform equally well regardless of the shape lacking any criticality over the prior art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Mon-Fri ( first Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LoAn H. Thanh  
Primary Examiner  
Art Unit 3763

LT